Massachusetts Department of Public Health
Division of Epidemiology and Immunization

General Protocols for Vaccine Storage, Administration, Standing Orders and Mass Immunization Clinics

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A. Persons Administering Vaccines

1. Health care providers who administer vaccine must have the legal authority to do so and shall be directly accountable for the safe and effective administration of immunizing agents. Furthermore, they must be appropriately trained in all aspects of vaccine administration including:
   - Proper storage and handling of vaccines;
   - Information to be elicited from patient or parent/legal representative before vaccination;
   - Information to be given to patient or parent/legal representative before vaccination;
   - Techniques for vaccine administration; and
   - Ability to handle and report adverse reactions.

2. Health care providers who administer vaccine should have evidence of immunity or be immunized against measles, mumps, rubella, varicella, hepatitis B, influenza, tetanus diphtheria, and pertussis.

B. Screening Patients Prior to Vaccination

1. Screen patients for eligibility for vaccination. Eligibility is based on:
   - The patient's age;
   - The patient's vaccination status (e.g., persons previously unvaccinated or due for vaccination according to the recommended schedule); and
   - The presence of a medical condition that puts them at high risk.

You can develop your own screening questionnaire or make use of preexisting screening questionnaires from the Immunization Action Coalition at www.immunize.org

2. Screen for contraindications: A contraindication is a condition in a recipient that increases the risk for a serious adverse reaction. A vaccine should not be administered when a contraindication is present.
   - At minimum, obtain information regarding vaccines previously received, preexisting health conditions, allergies, and adverse events that occurred after previous vaccinations.
   - If a potential vaccine has a contraindication or precaution, refer them to the Medical Director on site, or to their primary care provider.
   - Severe allergic reactions to a vaccine component or after a previous dose are very rare events, but, are a contraindication to a subsequent dose.
   - For information about vaccine additives and ingredients please refer to: CDC (2009) Epidemiology and Prevention of Vaccine-Preventable Diseases (The Pink Book) Appendix B: http://www.cdc.gov/vaccines/pubs/pinkbook/pink-appendx.htm#appb.
   - Physical examination and vital signs (i.e., temperature, blood pressure, pulse, respirations) measurement are not necessary before or after administration of vaccines, unless specifically indicated.
   - Assessment of patient's physical condition can be based exclusively on information elicited from the patient, parent or guardian and on the provider's observations of the patient's condition.
   - Breastfeeding does not adversely affect immunization and is not a contraindication for any vaccine with the exception of small pox vaccine.
   - Anyone for whom vaccine is deferred because of a contraindication should be referred to their primary care provider for evaluation and confirmation of the contraindication.

3. Screen for precautions: A precaution is a condition in a recipient that might increase the risk for a serious adverse reaction or that might compromise the ability of the vaccine to produce immunity. In general, vaccinations should be deferred when a precaution is present.

However if the benefits of vaccination clearly outweigh the risk of an adverse reaction, vaccination may be indicated.

- The presence of a moderate or severe illness with or without fever is a temporary precaution to administration of all vaccines.
- All vaccines can be administered to persons with minor acute illness (e.g., diarrhea, mild upper respiratory tract infections with or without fever).
- Antimicrobial therapy is not a precaution to administration of vaccines unless the person is moderately to severely ill.
- Theoretically there is a concern that live vaccines may suppress Tuberculin Skin Test (TST). Live vaccines and TST can be administered at the same visit. However, if the live vaccines were administered recently, skin testing should be delayed for at least four (4) weeks. If TST screening was administered prior to needing live vaccines, once the test is read, live vaccines can be administered.

For a complete list of vaccine contraindications and precautions see CDC's Guide to Vaccine Contraindications and Precautions at http://www.cdc.gov/vaccines/recs/vac-admin/downloads/contraindications_guide.pdf .

4. Latex allergies: Dry natural rubber is used in syringe plungers and vial stoppers. Dry natural rubber and natural rubber latex contain the same impurities (e.g., plant proteins and peptides) believed to be responsible for allergic reactions, but in lesser amounts than latex. Allergic reactions (including anaphylaxis) after vaccination procedures are rare. Only one report of an allergic reaction after administering hepatitis B vaccine in a patient with known severe allergy (anaphylaxis) to latex has been published.

   A person with a history of an anaphylactic reaction to latex should be referred to a health care provider for evaluation and safe administration of vaccines. For latex allergies other than anaphylactic allergies (e.g., history of contact allergy to latex gloves), vaccines supplied in vials or syringes that contains dry natural rubber of natural rubber latex can be administered.

   For additional information, refer to CDC (2009) Epidemiology and Prevention of Vaccine-Preventable Diseases (Pink Book) Appendix B, PG. B-18 at www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/latex.table.pdf .

C. Patient Education Requirement

1. All providers are required to provide patient, parent or legal representative with adequate information regarding the risks and benefits of a vaccine, and answer any questions. CDC-developed Vaccine Information Statements (VISs), which provide this information, must be used for all vaccines for which they have been developed (42 U.S.C. Section 300aa-26). The

most current version of the appropriate VIS must be used for each dose of vaccine administered. Each patient, or the parent/legal representative, must receive a copy of the form prior to administration of the vaccine.

Copies of the most recent VISs are available online and can be downloaded from the Immunization Action Coalition Website (www.immunize.org/vis). They are also available on the CDC website: www.cdc.gov/vaccines/publications/VIS and can be downloaded directly into a personal mobile device. You can also subscribe for email notification when a VIS is updated or a new VIS becomes available.

Provide non-English speakers with VISs in their own language, if available. VISs in foreign languages for most vaccines are available at www.immunize.org/vis.

2. Appropriate materials and information may be substituted only if VISs are unavailable. This information should be culturally and linguistically appropriate and written at a reading level that can be easily understood.

   The National Childhood Vaccine Injury Act requires providers to supplement the VISs with "visual presentations" or "oral explanations" as needed. If patients are unable to read the VISs, it is up to the provider to ensure that they have access to the information they contain.

   VISs can be read to these patients, or videotapes can be used as supplements. At least one CD-ROM is being produced on which users can hear the VISs read. Audio files and versions of VISs that are compatible with screen reader devices are available on CDC's VIS website.

3. Providers must address questions and concerns posed by the patient or parent/legal representative.

   There is no federal or state requirement to obtain signed consent or documentation that the patient has received a VIS. The exception to this is when parents or legal guardians are not present.

4. Providers must record any patient refusals or medical contraindications.

D. Consent and Education Requirements When Parent or Legal Representative Not Present

1. While there is no federal requirement for a signature to be obtained prior to immunization, state law generally requires the consent of a parent or legal representative regarding the treatment of minors, if the parent or legal representative is not present. However, there are federal policies relating to signatures acknowledging receipt of the Vaccine Information Statements (VISs), which must be part of the consent process.

In school-based programs, or other programs where the parent or legal representative is not likely to be present at the time of immunization, the parent or legal representative may either:

- Sign an individual consent form for the administration of each dose of vaccine, which includes acknowledging receipt of the VIS prior to each dose; or
- Sign a single consent form for the administration of an entire vaccine series (e.g. hepatitis B vaccine), if permissible by the institution's legal counsel. Single signature consent forms must:
    - Have a place for the parent/legal representative acknowledging the receipt of the VIS and give permission for their child to be vaccinated with the complete series.
    - Describe the future process whereby the VIS shall be sent home prior to each subsequent dose.
    - State that a "Withdrawal of Permission Form" will be sent home with the VIS prior to each subsequent dose. This statement notifies the parent or legal representative that, based on their earlier permission, the next dose will be given (list the date), unless the parent or legal representative signs the "Withdrawal of Permission Form".

2. Establish procedures for responding to questions from parent or legal representative by telephone or mail.

3. In the patient's medical record, maintain the original consent signature(s), any "Withdrawal of Permission Forms", and dates the VISs were sent home to the parent or legal representative.

4. Consult with the institution's legal counsel about any policies or requirements specific to the institution regarding consent and consent forms.

E. Vaccine Storage and Handling

1. Providers will have written procedures for vaccine management, which include:
    - Designation of a Vaccine Manager and another staff person to be a back up.
    - Proper storage and handling.
    - Vaccine receiving.
    - Procedures for vaccine relocation in the event of a power or equipment failure.
    - Vaccine ordering and inventory control.
    - Handling lost and expired vaccine.
    - Protocols for response when vaccine is stored out of temperature range.

2. The provider agrees to follow the manufacturer's specifications and the guidelines established by the MDPH Immunization Program for the storage and handling of vaccines. Proper vaccine management includes:
   - All vaccines, with the exception of varicella, MMRV, and zoster vaccine (shingles vaccine) must be stored refrigerated at 2º to 8º C (35° to 46° F).
   - Vaccine inventory must be clearly marked or identified, so providers can differentiate between vaccines supplied by the Massachusetts Department of Public Health Immunization Program and vaccines which are privately purchased by the practice.
   - Varicella, MMRV, and zoster vaccine must be stored frozen at < -15º C (< 5º F).
   - The use of a small combination refrigerator/freezer unit that is outfitted with one external door is not acceptable for proper storage of vaccines.
   - Vaccines should not be stored on the refrigerator or freezer door or in storage bins.
   - Vaccines should be organized in refrigerator to maximize space and allow proper air flow.
   - Using a certified, calibrated, product temperature thermometer, temperatures must be recorded twice daily (AM and PM) for all vaccine storage units. Logs must be reviewed for completeness and out-of-range temperatures. Immediate action must be taken if temperatures are out of range. Report all vaccine storage and handling issues to the Vaccine Management Unit at 617-983-6828.
   - Temperature logs must be maintained for 3 years.
   - All providers are required to submit current temperature logs whenever vaccines are ordered with their vaccine order form and usage report to the Vaccine Management Unit.
   - All vaccine stock must be rotated so vaccine with shortest shelf life is used first.
   - Stabilize refrigerator and freezer temperatures with proper placement and use of water bottles and frozen packs.

3. Multi-dose vials that contain a bacteriostatic agent, usually thimerosal, can be used until the date of expiration once they are opened, unless the vial becomes visibly contaminated or is not stored at the correct temperature or the package insert indicates it has a particular shelf life after reconstitution or first use.

4. Multi-dose vials that require reconstitution must be used within an interval specified by the manufacturer. After reconstitution, the new expiration date should be written on the vial. For example, Menomune (meningococcal polysaccharide vaccine) must be discarded 35 days after reconstitution. Label open multi-dose vials with the date and time it has been opened.

5. Store vaccines separate from other medication and biologics. Do not store food or beverages in the same refrigerator or freezer as vaccines.

F. General Administration Guidelines

1. Administer immunization(s) per the vaccine-specific standing order and medical protocols, developed in accordance with the Recommendations of the Advisory Committee on Immunization Practices (ACIP), other national advisory documents, and vaccine package insert(s). Remember to always read the vaccine package insert(s) prior to vaccine administration.

2. Hand hygiene should be used before and after each new patient is immunized. Alcohol-based hand rubs or gels may be used. Occupational Safety and Health Administration (OSHA) regulations do not require gloves to be worn when administering vaccines unless there is potential for exposure to blood and body fluids, and the health care provider has open hand lesions.

3. Aspiration before injection of vaccines or toxoids (i.e. pulling back on the syringe plunger after needled insertion, before injection) is not required because no large blood vessels exist at the recommended injection sites.

4. After use, needles should not be recapped, detached, bent, cut, or broken. Providers shall ensure that any used needles are disposed of appropriately in sharps containers that are rigid, puncture proof and can be closed, preventing any needles from spilling out. The containers shall contain the appropriate labels for biohazard waste.

5. Syringes and needles must be sterile and preferably disposable, to minimize the chances of contamination. Changing needles between drawing a vaccine into the syringe and injecting it is not necessary, unless indicated in the package insert. A separate needle and syringe should be used for each injection. Different vaccines should not be mixed in the same syringe unless specifically licensed and labeled for such use.

6. Principles of Injection Safety (Association for Professionals in Infection Control and Epidemiology (APIC), WHO, CDC)
    - In order to reduce the incidence of needle-stick injuries among healthcare workers and the consequent risk for blood borne diseases acquired from patients, federal regulations now require that safer injection devices (e.g., needle-shielding syringes or needle-free injectors) be used for parenteral vaccination in all clinical settings when such devices are appropriate, commercially available, and capable of achieving the intended clinical purpose. Additional information is available on the OSHA website: www.osha.gov. and at http://www.cdc.gov/ncidod/dhqp/guidelines.html

- A safe injection is one that:
  - does no harm to the recipient,
  - does not expose the provider to any avoidable risks, and
  - does not result in waste that is dangerous for the community. http://www.who.int/injection_safety/en/
- Providers are reminded to follow the principles of injection safety. This includes the practice of one needle, one syringe, only one time; meaning using a needle and syringe only once, only on one patient.
- In addition, these principles require that hazards to healthcare workers are minimized. By meeting the requirements of the OSHA Blood Borne Pathogen Standard and MDPH regulations, through the use of devices with engineered sharps injury protections, risk of a needle stick injury is reduced. Providers are reminded that they must select needles with built in sharps injury prevention features to attach to any prefilled syringes or to use to administer vaccines drawn up from a multi-dose vial.
- The person who prepares the vaccination should be the same person who administers the vaccination. Pre-drawing of immunizations in a non-mass vaccination clinic setting (e.g., provider office) is discouraged. If syringes are pre-filled in a non-mass vaccination clinic setting, they should be stored in the refrigerator, used on the same day they are filled, and they should be labeled for identification purposes.
- MMR, yellow fever and varicella containing vaccines should be stored in their boxes until they are ready to use, and they should never be drawn up ahead of time.
- Most vaccines are either administered by the intramuscular or subcutaneous route. Routes of administration are recommended by the vaccine manufacturer for each vaccine. Deviation from the recommended route of administration might reduce vaccine efficacy or increase local adverse reactions.
- Response to vaccines recommended by the subcutaneous route probably will not be affected if the vaccines are administered by intramuscular route rather than by the subcutaneous route. Repeating the dose is not necessary. Almost all vaccines recommended by the intramuscular route that are given subcutaneously should be repeated (exception: MCV4 given subcutaneously).

7. A brief period of bleeding at the injection site is common and can usually be controlled by applying gentle pressure for several minutes. Use of adhesive bandages on an injection site for more than 1 or 2 hours can mask an infection and is discouraged.

8. Personnel administering vaccines should consider using methods for alleviating patients' discomfort and pain associated with vaccination. The Advisory Committee on Immunization Practices (ACIP) suggests comfort measures and distraction techniques for children, cooling of the injection site, and topical and oral analgesia.

9. Whenever possible, patients should be observed for possible allergic reactions or syncope for 15 to 20 minutes after receiving immunizations. Facilities and personnel should be available to treat immediate hypersensitivity reactions regardless of the clinic setting (e.g., school located, or other non-clinic settings). For additional information, please see the MDPH Immunization Program's Standing Orders for Emergency Treatment. Please note, syncope following receipt of a vaccine is not a contraindication to subsequent doses.

10. Protocol for Anaphylaxis
    - Because of possible hypersensitivity to vaccine components, persons administering biologic products or serum should be prepared to recognize and treat allergic reactions, including anaphylaxis. The necessary medications, equipment, and staff competent to maintain the patency of the airway and to manage cardiovascular collapse must be immediately available. Vaccine providers must be in close proximity to a telephone so that emergency medical personnel can be summoned immediately, if necessary. Whenever possible, patients should be observed for an allergic reaction for 15 to 20 minutes after receiving immunization(s).
    - The following equipment and supplies should be readily available at every site at which immunizations are administered:
      - Sphygmomanometer and stethoscope
      - Emergency medications:
        - Epinephrine 1:1000 (aqueous) for injection or EpiPens®
        - Diphenhydramine hydrochloride (Benadryl®) - PO and injectable
        - Steroids (optional)
      - Syringes:
        - 1 cc syringes with 1 – 1½ inch needles (for epinephrine administration)
        - 1 and 2 cc syringes, with 1 – 1½ inch needles (for Benadryl® administration)
        - Oral airways (small, medium and large)
        - Alcohol wipes and band aids
        - A plan in place to contact emergency medical services if the need arises

G. Documentation Requirements

1. Providers must ensure that the permanent medical record of the recipient (or a permanent office log or file) contains all the required documentation. This documentation shall consist of the following:
   - Date of administration of the vaccine,
   - Vaccine manufacturer and lot number of the vaccine,
   - Name, address and title of person administering the vaccine,

   - Edition date printed on the appropriate VIS, and
   - Date the VIS was given to the vaccine recipient, or the parents/legal representative.

We also recommend that the vaccine type, dose, site and route of administration be documented. Copies of vaccine administration records which can be used in your office are available by visiting http://www.mass.gov/dph/imm and selecting "Guidelines and Schedules".

If relevant, also record

- Any preexisting conditions
- Date the next dose is due

Note: A diluent that is licensed separately has a separate lot number that must be documented separately (e.g., DTaP-IPV/Hib combination vaccine).

2. Requirements for retention of written documentation vary and depend on licensing specifications.
   - Clinics and hospitals must retain written documentation for a period of 30 years after the discharge or final treatment of the patient. All other facilities, e.g., doctors' offices, BOHs, VNAs, nursing homes, etc., must retain documentation for a period of 10 years following the end of the last calendar year in which the documentation occurred (NCVIA 1986).

3. Provide the patient or parent/legal representative with a vaccine card documenting the vaccines given and the date the next doses are due.

Additional information about vaccines storage, administration, documentation and reporting can be found in the MDPH document *Guidelines for Compliance with Federal and State Vaccine Administration Requirements* available at http://www.mass.gov/Eeohhs2/docs/dph/cdc/immunization/guidelines_vaccine_compliance.pdf

H. Post-Vaccination Adverse Event Reporting Requirements

1. Any post-vaccination adverse event(s) must be reported to the Vaccine Adverse Event Reporting System (VAERS). The appropriate VAERS forms and contact information should be readily available. Report all clinically significant events to VAERS, regardless of whether or not you believe the events are caused by the vaccine. Public clinics that are sponsored by boards of health or Visiting Nursing Associations, should report adverse events to the MDPH Immunization Program, 617-983-6800.

2. Private providers should forward their report to the ERC Bioservices Corporation using VAERS forms or call 1-800-822-7967. Providers can now submit VAERS reports via the internet at: www.vaers.ehhs.gov .

3. Please report administration errors to the Institute for Safe Medical Practices (ISMP) via the Medication Error Reporting Program (MERP) website: http://www.ismp.org.

   In addition, report any post-vaccination adverse event to the patient's primary care provider or their local board of health (if no such provider is identified). Also, encourage patients or their parents/legal representatives to report any post-vaccination adverse event that occurs after they leave your facility to their primary care provider or their local board of health (if no such provider is identified).

4. Provide the patient's primary care provider or local board of health (if no such provider can be identified) with a record of the relevant information about the immunization(s) given, including any adverse events.

5. Encourage patients or parents/guardians to inform their primary care provider or their local board of health (if no such provider can be identified) of any adverse event(s) following immunization after they leave your facility.

6. The patient or the parent/legal representative should be informed of the importance of having a medical home (i.e. primary care provider) and receiving other preventive medical services.

I. Additional Documentation Requirements for Mass Immunization Clinics

1. Keep a registration sheet for patients attending each clinic. Include name, address or department, telephone number, appointment time, age and date of clinic.

2. Establish a system for central storage of all documentation relating to vaccine administration. This will include any tear off sheets, vaccine administration records or registration sheets.

3. If more than one type of vaccine is administered to a patient, a separate vaccine administration record must be used for each type of vaccine. An option may be to use a different color paper for each vaccine administration record.

4. Recommendations for drawing up vaccine
   - When drawing up vaccine in preparation for mass immunization clinics or clinical sessions, three issues must be considered:
     - Viability of the vaccine;
     - Ability to identify the vaccine in the syringes
     - Avoiding vaccine wastage

i. Viability of vaccine.

- Vaccines should be drawn up as close to the time of administration as possible. Once the vaccine is drawn up, it should be placed in the refrigerator or in containers with cold packs. Under no circumstances should MMR or varicella-containing vaccines (varicella, MMRV and zoster vaccines), ever be reconstituted and drawn prior to the immediate need for them. These live virus vaccines are unstable and begin to deteriorate as soon as they are reconstituted with diluent.
- Environmental conditions, such as heat and light, can affect the viability of the vaccines, and vaccines vary as to their stability.
- In order to ensure the viability of vaccines, there are specific restrictions regarding MMR, varicella-containing vaccines, yellow fever, Tripedia®-ActHIB® [TriHIBIT®], and DTaP-IPV/Hib (Pentacel®) vaccines (see table in Appendix A).
- If there are any questions about the viability of a vaccine, consult the MDPH Immunization Program vaccine management unit at 617-983-6828 or the vaccine manufacturer. Mishandled or expired vaccine administered should not be counted as valid doses. Patients should be age-appropriately revaccinated. Alternatively, depending on the age of the recipient and the number of doses received, patients could be tested to ensure immunity for those antigens (measles, mumps, rubella, varicella, hepatitis B, hepatitis A, Haemophilus influenzae type b (Hib), diphtheria, and tetanus) for which serologic correlates of immunity exist and are readily available.

ii. Ability to identify vaccine in the syringes.

In order to reduce the risk of medication administration errors, CDC strongly discourages pre- filling syringes. In situations where pre-filling syringes is unavoidable, medication administration errors may be avoided by storing syringes with vaccines of the same type and same lot number together in separate or divided containers or trays.

- Label each syringe with:
  - type of vaccine
  - lot number
  - date and time vaccine was drawn up
  - initials of the person who drew up the vaccine.
- Label each container or tray with type of vaccine.

Syringes other than those filled by manufacturer must be discarded at the end of the day.

iii. Avoiding vaccine wastage

In order to avoid vaccine wastage:

- Do not draw up more vaccine than will be used at the clinic or session.
- Ensure the cold chain is maintained until the vaccine is administered.

- Adhere to sterile technique when drawing up the vaccine.

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Appendix

Table. Viability of Select Vaccines After Reconstitution

Vaccines	Time frame for use post reconstitution	Environmental conditions to avoid
ActHIB® vaccine	must be used < 24 hours after reconstitution	
MMR vaccine	should be used as soon as possible after reconstitution MMR vaccine not used < 8 hours after being reconstituted must be discarded	Cold (refrigerated) diluent should be used to reconstitute MMR vaccine that will not be used immediately. Vials and syringes with MMR vaccine should be protected from light at all times
Pentacel	Use immediately after reconstitution	
MMRV	Use immediately after reconstitution	Protect from light at all times
Tripedia®	must be used < 8 hours after reconstitution with saline	
Tripedia®-ActHIB® [TriHIBIT®] vaccine	must be used < 30 minutes after reconstitution	
Varicella vaccine	must be used < 30 minutes after reconstitution	Keep frozen before reconstitution
Yellow fever vaccine	must be used < 1 hour after reconstitution	
Zoster Vaccine	must be used < 30 minutes after reconstitution	Protect from light before reconstitution